

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/725,752	TOKUNAGA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Diana B. Johannsen	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment of July 25, 2003 and the interview of December 31, 2003.
2. ☒ The allowed claim(s) is/are 16 and 17.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                           |                                                                                            |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>0104</u> . |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                         |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                   |
|                                                                                                           | 9 <input type="checkbox"/> Other _____                                                     |

### **EXAMINER'S AMENDMENT**

1. This action is in response to the Amendment filed July 25, 2003 and to the Interview concluding December 31, 2003. Claims 10-11 and 14 were canceled by the Amendment of July 25, 2003; accordingly, the rejections of those claims set forth in the Office Action of April 25, 2003 are moot. Non-elected claims 1-9, 12-13 and 15 are canceled by the below Examiner's amendment. Newly added claims 16-17, as amended by the below Examiner's amendment, are now allowed.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Warren M. Cheek, Jr. on December 31, 2003.

3. In accordance with 37 CFR 1.126, allowed claims 16-17 will be renumbered as claims 1-2, respectively (see *MPEP* 608.01(j)). It is noted that original claim numbers are employed in the below Examiner's amendment.

4. **Cancel claims 1-9, 12-13, and 15.**

5. **Amend claims 16-17 as follows:**

16. A method for diagnosing Crohn's disease, which comprises the steps of

(a) taking a biological sample from a human ~~that has developed or is associated with a risk of developing Crohn's disease~~, the sample being obtained from colon tissue or intestine ileum tissue, and

(b) analyzing the level of gene expression of at least one gene selected from the group consisting of a gene encoding type 6 protein phosphatase regulated by interleukin 2, a gene encoding a Traf 2 and Nck interacting kinase, a gene encoding FLICE inhibitory protein and a gene encoding glucocorticoid receptor  $\alpha$ , in the biological sample, wherein ~~an increased level~~ up-regulation of gene expression is an indicator of Crohn's disease, thereby diagnosing Crohn's disease and

~~(c) diagnosing Crohn's disease based upon a finding of an increased level of gene expression.~~

17. The method for diagnosing Crohn's disease according to claim 16, which further comprises analyzing the level of gene expression of at least one gene selected from the group consisting of a gene encoding cytochrome oxidase subunit 1 ~~gene~~ and a gene encoding cytochrome b.

***Substance of Interview concluding December 31, 2003.***

6. On December 22, 2003, the examiner contacted Applicants' representative to propose amendments that would further clarify newly added claims 16 and 17 and place those claims in condition for allowance. The examiner also proposed canceling non-elected claims 1-9, 12-13 and 15. On December 31, 2003, Applicants' representative agreed to the examiner's proposal.

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, horizontal, sweeping line that extends to the right.

Diana B. Johannsen  
Patent Examiner  
January 24, 2004